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TRASKBRITT, P.C. P.O. BOX 2550 SALT LAKE CITY, UT 84110			KIM, TAEYOON	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/646,615	Applicant(s) HENNEN, WILLIAM J.
	Examiner TAEYOON KIM	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 02 June 2009.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-4,8,11,12,14-16,18,50,53-57 and 59-80 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-4,8,11,12,14-16,18,50,53-57 and 59-80 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

Applicant's amendment and response filed on 6/2/2009 has been received and entered into the case.

Claims 2, 3, 9, 10, 13, 17, 19-49, 51, 52 and 58 are canceled, and claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57 and 59-80 are pending and have been considered on the merits. All arguments have been fully considered.

Response to Amendment/Argument

The claim objection has been withdrawn due to the amendment.

Claim Rejections - 35 USC § 112-New Matter Rejection

Applicant's arguments with regard to the new matter rejection have been fully considered but they are not persuasive.

Applicant alleged that the term of "vitamin-like substance" is a term of art and cited a webpage providing the definition of the term. The new matter rejection is based on the written description requirement, not a question of what one of skill in the art would or would not have known.

M.P.E.P. §2163 states "To comply with the written description requirement of 35 U.S.C. 112, para. 1, or to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure. When an explicit limitation in a claim "is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation." *Hyatt v. Boone*, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998). See

also *In re Wright*, 866 F.2d 422, 425, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989) (Original specification for method of forming images using photosensitive microcapsules which describes removal of microcapsules from surface and warns that capsules not be disturbed prior to formation of image, unequivocally teaches absence of permanently fixed microcapsules and supports amended language of claims requiring that microcapsules be "not permanently fixed" to underlying surface, and therefore meets description requirement of 35 U.S.C. 112.); *In re Robins*, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (CCPA 1970) ("[W]here no explicit description of a generic invention is to be found in the specification[,] ... mention of representative compounds may provide an implicit description upon which to base generic claim language."); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily implicitly described by a genus encompassing it and a species upon which it reads); *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) ("To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'") (citations omitted). Furthermore, each claim must include all elements which applicant has described as essential. See, e.g., *Johnson Worldwide Associates Inc. v. Zebeo Corp.*, 175 F.3d at 993, 50 USPQ2d at 1613; *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d at 1479, 45 USPQ2d at 1503; *Tronzo v. Biomet*, 156 F.3d at 1159, 47 USPQ2d at 1833.

Furthermore, M.P.E.P. §2163 recites, "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by

actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus...when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus."

Still further, M.P.E.P. § 608.04 discloses "If the new matter has been entered into the claims or affects the scope of the claims, the claims affected should be rejected under 35 U.S.C. 112, first paragraph, because the new matter is not described in the application as originally filed."

Applicant asserted that the disclosure of coenzyme Q10 in the specification is sufficient to support the term "vitamin-like substance". While coenzyme Q10 might be considered as one example of the genus of the vitamin-like substance, the disclosure of coenzyme Q10 does not necessarily require the entire genus of "vitamin-like substance" for the claimed invention. Furthermore, the disclosure of a single species would not sufficiently represent the entire genus. Still further, even if Co Q10 is considered a species for the vitamin-like substance, the new generic limitation introduces broader limitation (genus) to the originally filed claims. Therefore, the introduction of "vitamin-like substance" is considered to change the scope of the originally filed claims and thus considered as a new matter.

The same analysis is applicable to the term "herb or plant extract". As applicant argued,

the specification of the instant application discloses butcher's broom, Ginkgo biloba, hawthorn, garlic, reservatrol, or ginger oil. However, the specification does not disclose the genus of herb or plant extract, and these species are not considered to encompass the entire scope of "herb" or "plant extract". Since there is substantial variation within the genus, and the specification did not provide adequate description for the entire genus or even for the species, the introduction of generic limitation in the current amendment is not considered to be satisfied for the written description requirement. See M.P.E.P. §2163.05(I).

With regard to the term "a carrier" in claims 79 and 80, applicant failed to argue against the rejection, and thus, the holding of the rejection is a must.

It is noted that claims 72-78 was inadvertently included in the claim rejection as indicated by applicant. It is acknowledge that claims 72-78 are not rejected under 35 U.S.C. §112.

The claim rejection under 35 U.S.C. §112, 1st par., to the limitation of LDL-receptor-binding component, a blood cholesterol reduction component, blood cholesterol reducing element, blood flow-enhancing component or fat oxidation prevention element, has been withdrawn.

Claim Rejections - 35 USC § 103

Applicant's arguments with respect to claims 1, 7, 8, 11, 12, 14-16, 18, 50, 56, 57, 59-67 and 72-78 have been fully considered but found not persuasive. It is noted that the current claim rejection has been reconstructed based on the references cited previously. It is also noted that the rejection to claims 79 and 80 has been withdrawn.

In response to the claim rejection under 35 U.S.C. §103 in the previous OA, applicant argued that the OA has not articulate any specific reason for one of ordinary skill in the art to

have combined teachings from the cited references, and the only reason for combining the teachings of these references was to improperly rely upon hindsight to reconstruct the compositions recited by the rejected claims.

This argument has been fully considered but found not persuasive. The claim rejection in the previous OA, the reason to combine the references was clearly indicated that duplication of the components with similar functions within a composition is obvious citing M.P.E.P. §2144.04.

Furthermore, M.P.E.P. §2144.06 states "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant's argument with respect to the teaching of Szapary is persuasive, and thus the rejection to claims 79 and 80 is withdrawn.

With regard to the amount of transfer factor and vitamin C, applicant alleged that the office action did not articulate any reasoning to support its rejection. This is not persuasive. The claim rejection in the previous OA discussed the issue and indicated that the limitation is considered as routine optimization in the absence of the evidence to the contrary (see p.11-12).

Applicant also asserted that while Campbell teaches that Chlamydia pneumonia causes acute respiratory disease, none of the references teach or suggest a composition that includes transfer factor specific for Chlamydia pneumonia, or any of HSV type I, type II, cytomegalovirus or Helicobacter pylori. This argument is not persuasive.

First, Kirkpatrick discloses transfer factor specific for HSV (col. 4, lines 32-36).

The previous OA also clearly discussed that Campbell et al. teach that HSV along with other pathogens such as cytomegalovirus, H. pylori, or C. pneumoniae is associated with cardiovascular disease, and since it is well known in the art that transfer factor can be made specific to pathogens, it would have been obvious to a person of ordinary skill in the art to use transfer factors specific for pathogens associated with cardiovascular diseases including cytomegalovirus, H. pylori, or C. pneumoniae as a cardiovascular support component.

With respect to the claim rejection based on Tokoro, applicant argued that Tokoro does not provide any teaching or suggestion of a composition that includes transfer factor. Applicant further asserted that the teachings of Tokoro are limited to a transfer factor-like substance that the art indicates is something other than transfer factor. This argument is not persuasive in the absence of evidence that the transfer factor-like substance of Tokoro is different entity from transfer factor of claimed invention.

With regard to other argument for the claim rejection based on Tokoro, the arguments are moot in view of new ground of rejection shown below.

Claim Objections

Claim 62 is objected to because of the following informalities: There are two

typographical errors in the claim (line 2 and 3). The term “lest” or “lseat” should be “least”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112 - New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, 59-71, 79 and 80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the amendment filed on 12/9/2008, claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, 59-71, 79 and 80 disclose the transitional phrase of “consisting of”. Since the specification of the original application fails to disclose any embodiment supporting the transitional phrase of “consisting of”, and the newly introduced term changes the scope of the claims, the transitional phrase of “consisting of” in the claims is considered as a new matter.

In amended cases, subject matter not disclosed in the original application is sometimes added and a claim directed thereto. Such a claim is rejected on the ground that it recites elements without support in the original disclosure under 35 U.S.C. 112, first paragraph, *Waldemar Link, GmbH & Co. v. Osteonics Corp.* 32 F.3d 556, 559, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994); *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). See MPEP § 2163.06 - § 2163.07(b) for a discussion of the relationship of new matter to 35 U.S.C. 112, first paragraph.

New matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific percentages or compounds after a broader original disclosure, or even the omission of a step from a method.

M.P.E.P. § 608.04 discloses “If the new matter has been entered into the claims or affects the scope of the claims, the claims affected should be rejected under 35 U.S.C. 112, first paragraph, because the new matter is not described in the application as originally filed.”

The original disclosure of the current application uses the broader limitation using the transitional phrase of “comprising”. Since the phrase of “consisting of” changes the scope of the broader original disclosure to a narrow scope, the new transitional phrase of “consisting of” is considered as a new matter.

The newly introduced limitation of “vitamin-like substance” or “herb or plant extract” in the claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57 and 59-71 does not have a proper written descriptive support from the specification and the new limitation changes the scope of the claims to broader than the scope of the original claims.

The specification fails to disclose the limitation of “vitamin-like substance”. Although the definition of the term is known in the art, and as argued by applicant, CoQ10 is one example of such genus, it is not considered that Co Q10 is sufficiently representing the entire scope of “vitamin-like substance”.

The claimed invention appears to have specific herb or plant extract such as those having benefit to cardiovascular health. However, the subject matter claimed in the amendment introduces broader scope to the invention encompassing any herb or any plant extract. Since

there is substantial variation within the genus, and the specification did not provide adequate description for the entire genus, the introduction of generic limitation in the current amendment is not considered to be satisfied for the written description requirement. Thus, the limitation introduces a new matter to the current application.

Claims 59 and 62 introduce a new limitation of the at least one mineral comprising an LDL receptor-binding component or an antioxidant, respectively. The specification failed to disclose any mineral being an LDL receptor-binding component or an antioxidant. Therefore, the limitations are considered as a new matter.

Similarly, the new limitation of “a carrier” in claims 79 and 80 introduces a new matter to the application. There is no adequate support for the limitation in the specification.

Claim Rejections - 35 USC § 112 – Enablement Rejection

Claims 59, 60 and 62-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The current claims are drawn to the one mineral comprising an LDL receptor-binding component and the LDL receptor-binding component comprising lysine.

Since the subject matter is drawn to a mineral and it is extremely well known in the art that lysine is not a mineral. The specification failed to disclose that the mineral comprises LDL

receptor-binding component such as lysine.

Claims 62-65 are drawn to the at least one mineral comprising an antioxidant, and the antioxidant comprising beta-carotene, vitamin A, vitamin E or Co Q10.

Since the subject matter is drawn to a mineral and it is extremely well known in the art that the examples listed are not a mineral. The specification failed to disclose that the mineral comprises an antioxidant such as beta-carotene, vitamin A, vitamin E or Co Q10.

Therefore, the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to make the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-7, 8, 11, 12, 14-16, 18, 50, 53-57 and 59-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Vester (of record) in view of Kirkpatrick et al. (of record), Campbell et al. (of record), Rath et al. (of record), Tentolouris et al. (of record) and Kemper (of record) in further view of Tokoro (of record).

It is noted that claims 1, 4-7, 8, 11, 12, 14-16, 18, 50, 53-57, 59-71 disclose the transitional phrase of "consisting of". However, since each of the ingredients of the composition is disclosed as genus, any ingredient which is known to belong to each genus such as vitamin, mineral, herb or plant extract, LDL receptor-binding component, blood cholesterol reduction

component, blood flow-enhancing component or antioxidant is considered to be included to the claimed composition.

Vester teaches nutritional supplement for cardiovascular health. Vester teaches that minerals and/or trace elements such as magnesium, zinc, selenium, copper and potassium; vitamins A, C, E, B₆ and B₁₂; niacin (niacinamide or nicotinic acid); folate (folic acid); beta-carotene; CoQ10, and a carrier can be components of the supplement (col. 3-5).

Vester teaches an antioxidant, flavonoids being found in numerous vegetables or fruits (col. 2, lines 34-42), and thus, flavonoids are considered as plant extract satisfying the limitation of the claimed invention. Furthermore, flavonoids are considered to be a fat oxidation prevention element (col. 3, lines 23-30).

Since the ingredients disclosed in Vester are considered as a species belongs to the claimed generic components in one way or the other (e.g. flavonoids such as quercetin of Vester being an antioxidant or a plant extract), it is considered that ingredients of Vester meet the claimed limitation.

Vester does not teach transfer factor as a component of the nutritional supplement.

Kirkpatrick et al. teach a mammalian transfer factor specific for HSV (col. 4, lines 32-37) from colostrums extract.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to combine the transfer factor specific for HSV of Kirkpatrick et al. with the nutritional supplement of Vester.

The skilled artisan would have been motivated to make such a modification because Campbell et al. teach that HSV along with other pathogens such as cytomegalovirus, H. pylori,

or *C. pneumoniae* is associated with cardiovascular disease (p.573), and thus, a person of ordinary skill in the art would recognize that the transfer factor specific for HSV of Kirkpatrick et al. would have a benefit in treating or improving cardiovascular health.

M.P.E.P. §2144.06 states “It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. [T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

Furthermore, since it is well known in the art that transfer factor can be made specific to pathogens, it would have been obvious to a person of ordinary skill in the art to use transfer factors specific for cytomegalovirus, *H. pylori*, or *C. pneumoniae* as a cardiovascular support component as Campbell et al. teach that these pathogens are associated with cardiovascular diseases (Abstract and p.573).

With regard to the lysine or lysine salt (e.g. magnesium lysinate), Rath et al. teach lysine, which binds a LDL-receptor, for treatment of cardiovascular disease (abstract). Thus, a person of ordinary skill in the art would recognize the same purpose of treating and/or improving cardiovascular health from lysine or lysine salt as the nutritional supplement of Vester in view of Kirkpatrick et al. and Campbell et al.

With regard to the arginine or arginine salt (e.g. magnesium arginate), Tentolouris et al. teach that L-arginine administration improves the coronary blood flow suggesting that L-arginine

may have benefit in patients with risk factors for atherosclerosis (abstract).

It would have been obvious to a person of ordinary skill in the art to combine L-arginine or its well known salt form including arginate (e.g. magnesium arginate) of Tentolouris et al. with the nutritional supplement for cardiovascular health of Vester in view of Kirkpatrick et al., Campbell et al. and Rath et al.

With regard to the limitation drawn to the amount of transfer factor and vitamin C as in claim 72, it would have been obvious to a person of ordinary skill in the art to optimize the amount of the ingredient in the nutritional supplement of the references, since the concentration of components is considered as a result-effective variable. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Vester in view of Kirkpatrick et al., Campbell et al. Rath et al. and Tentolouris et al. do not teach that the transfer factor is non-mammalian, avian or from egg extract (claims 4-6, 53-55 and 68-71).

Tokoro teaches transfer factor from egg extract of immunized hen (see Examples).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to replace the source of the transfer factor from mammalian as of Kirkpatrick et al. to non-mammalian (e.g. avian) from egg extract as taught by Tokoro.

The skilled artisan would have been motivated to make such a modification because the production of transfer factor in a large amount from colostrums is difficult and limited due to its

production is limited to a few days, and furthermore necessitates a vast farm land according to Tokoro (see column 1, lines 39-49).

The person of ordinary skill in the art would have had a reasonable expectation of success in producing transfer factor of Kirkpatrick et al. from eggs of immunized hen since it has been successfully practiced in the art.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed. Claims 79 and 80 are free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAEYOON KIM whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Primary Examiner, Art Unit 1651